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5. 510(k) Summary

Submitter's Name: Fotona d.d.
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Contact Person: Stojan Trošt, QA&RA Manager
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FEB - 4 2009

Date: October 8, 2008

Device Name:
Trade name: Fotona XD Diode Laser System
Common name: Diode Surgical Laser
Classification name: Instruments, Surgical, Powered, Laser
79-GEX

DEVICE DESCRIPTION

The Fotona XD Diode Laser System is based on a semiconductor laser that operates in the near-infrared range of the electromagnetic spectrum. The laser source consists of a compact semiconductor laser diode module that emits laser light at a wavelength of 810 nm in continuous wave mode or pulse operation mode from 20 Hz to 10 kHz. The output power can be set from 250 mW to 7.0W. A red diode aiming beam (650 nm) is combined with the therapeutic laser beam and both beams are guided through an optical fiber delivery unit and an optical handpiece to the treatment site.

INTENDED USE

The **Fotona XD Diode Laser System**, and its accessories, are intended for use in

- **Periodontology** for
  - Laser soft tissue curettage
  - Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket
- **Oral Soft Tissue surgery** for
  - Gingivectomy
  - Gingivoplasty
  - Fibroma removal
  - Treatment of Aphthous Ulcers
  - Crown Lenghtening
  - Frenectomy
  - Papillectomy
  - Photocoagulation

- **Cosmetic Dentistry** for
  - Light activation for bleaching materials for teeth whitening
  - Lasers-assisted bleaching/whitening of the teeth

STATEMENT OF SUBSTANTIAL EQUIVALENCE

The Fotona XD Diode Laser System shares the same indications for use, similar design and functional features with, and therefore Fotona d.d. believes that its Fotona XD Laser System is substantially equivalent to, the

a) Odyssey 2.4G Diode Laser (K050453) previously cleared for a variety of surgical procedures on soft tissue within the oral cavity;

b) Opus 10 Dental Diode Laser System (With Tooth Whitening Application) (K011769) previously cleared for incision, excision, ablation, vaporization and/or coagulation (hemostasis) of oral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva). In addition, the system is intended for teeth whitening.

Details are provided in the Substantial Equivalence Discussion Section of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2009

Fotona D.D.
% Mr. Stojan Trost
Stegne 7
Ljubljana
Slovenia 1210

Re: K083034
Trade/Device Name: Fotona XD Diode Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 19, 2009
Received: January 23, 2009

Dear Mr. Trost:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): k083034

Device Name: **Fotona XD Diode Laser System**

Indications For Use:

Periodontology
- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket

Oral Soft Tissue surgery
- Gingivectomy
- Gingivoplasty
- Fibroma removal
- Treatment of Aphthous Ulcers
- Crown Lenghtening
- Frenectomy
- Papillectomy
- Photocoagulation

Cosmetic Dentistry
- Light activation for bleaching materials for teeth whitening
- Lasers-assisted bleaching/whitening of the teeth

Prescription Use: __X___ AND/OR Over-The-Counter Use:_____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number k083034